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The Office Action

The Examiner rejects claims 1, 2, 4, 6, 11, 13, 15, and 16 as being obvious over Byers (US 4,969,468) in view of Owen (US 6,148,233).

Claims 3 and 5 have been cancelled.

Claims 7 and 10 stand rejected under 35 U.S.C. § 102 as being anticipated by Byers. Claim 10, it will be noted, depends from claim 9, which, in turn, depends from claim 8, which, in turn, depends from claim 7. Intervening claims 8 and 9 are not rejected under 35 U.S.C. § 102.

Claims 8 and 9 stand rejected under 35 U.S.C. § 103 as being unpatentable over Byers.

Claims 12 and 14 stand rejected under 35 U.S.C. § 103 as being unpatentable over Byers in view of Ingman (US 2002/0082668). Claim 14, it will be noted, depends from claim 13, which stands rejected on a different combination of references.

The Rejection is Inconsistent

First, the Examiner rejects dependent claims 8 and 9 under 35 U.S.C. § 103. Yet, dependent claim 10, which depends from claim 9, which depends from claim 8, has been rejected under 35 U.S.C. § 102. Because a dependent claim is read as incorporating the subject matter of its parent claims, it is not understood how dependent claim 10 can be rejected under 35 U.S.C. § 102 as being anticipated by Byers when its parent claims 8 and 9 contain subject matter which the Examiner acknowledges is not found in Byers.

Similarly, claim 14 depends from claim 13. Claim 13 has been rejected as being obvious over Byers in view of Owen. Claim 14, which includes the subject matter of its parent claim 13 plus additional limitations, has been rejected over Byers in view of Ingman. The Examiner has not asserted that Ingman supplies the same subject matter as Owen and, indeed, it does not. It is not understood how the subject matter of parent claim 13, which the Examiner cited Owen to supply, can be ignored when rejecting claim 14.

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**The Claims Distinguish Patentably Over
The References of Record**

Claim 1 calls for projections of electrically conductive elastic material. The Examiner's assertion that projections of an electrically conductive elastic material are found in Byers is not well-founded.

First, the Examiner has declined to identify the portion of Byers which discloses such feature, when clarification was previously requested. Accordingly, the subject Office Action does not establish a *prima facie* case because it does not *identify* which feature(s) of the cited reference corresponds to the claimed projections of electrically conductive elastic material. To meet the burden of establishing a *prima facie* case, the Office must explain how the rejected claims are anticipated by pointing out where the specific elements of the claims are found in the prior art. *Ex Parte Naoya Isoda*, Appeal No. 2005-2289, Application 10/064,508 (Bd. Pat. App. & Inter.2005).

The goal of examination is to clearly articulate any rejection early in the prosecution process so that the applicant has the opportunity to provide evidence of patentability and otherwise reply completely at the earliest opportunity. (MPEP §706). This goal has not been met. The Examiner was previously asked for clarification. Clarification was not provided. Accordingly, the applicant has not been given the opportunity to provide evidence of patentability or to reply completely. A final Office Action is believed to be inappropriate under these circumstances.

Furthermore, the pertinence of each reference, if not apparent, must be clearly explained and each rejected claim specified. (37 C.F.R. §1.104(c)(2)). Applicants respectfully submit that the pertinence of the Byers reference has not been clearly explained.

Notwithstanding the Examiner's failure to establish a *prima facie* case (by failing to identify the portion of Byers which allegedly discloses the claimed projections of electrically conductive elastic material), Applicants will attempt to address the present rejection solely for the purpose of advancing prosecution. Applicants do not acknowledge any duty to rebut the Examiner's rejection given the Examiner's failure to establish a *prima facie* case in the first place.

Byers discloses that the base is flexible, curved, or stretchable. There is no suggestion in Byers that the needles be made of an electrically-conductive elastic

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material. As described in columns 1 and 2 of Byers, a primary design criteria is the development of an implantable electrode which engages with fibers of a nerve to which it is attached. As set forth in column 8, line 64 – column 9, line 55, the needles are designed to be extremely thin so as to penetrate between the fibers of the nerve without damaging the nerve. It is submitted that elastic needles would not fulfill this design criteria. Although Byers does acknowledge other uses for the electrode, the design criteria are based on interacting with a patient's nerve.

Throughout the reference, Byers describes needles which penetrate. It is submitted that not only does Byers not suggest that the needles could be flexible, curved, or stretchable, but that making the piercing needles of such a construction would be contrary to the design criteria of Byers and render the Byers electrode unsuitable for its intended purposes.

Second, the Examiner erroneously equates flexible and stretchable with elastic. While elastic materials are often flexible and stretchable, stretchable and flexible materials are not necessarily elastic. Elasticity connotes something more than flexible or stretchable. Specifically, it connotes shape memory. The elastic materials are materials which exhibit the property of elasticity. Elasticity, according to the *Concise Encyclopedia of Polymer Science & Engineering*, Wiley & Sons, Copyright 1990, defines "elasticity" as:

Elasticity is a reversible stress-strain behavior by which a body resists and recovers from deformation produced by a force. This behavior is exhibited by rubberlike materials in a unique and extremely important manner. Unlike metals or glasses, they can undergo very large deformations without rupture (and are thus similar to liquids) and then come back to their original shape (as do solids).

Similarly, the *McGraw-Hill Concise Encyclopedia of Science & Technology*, Third Edition, Copyright 1994, defines "elasticity" as:

The property whereby a solid material changes its shape and size under the action of opposing forces, but recovers its original

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configuration when the forces are removed. The theory of elasticity deals with relations between the forces acting on the body and the resultant changes in configuration, and is important in many branches of science and technology, for instance, in the design of structures, in the theory of vibration and sound, and in the study of the forces between atoms and lattices.

Thus, the metal foil described in Byers, while it may be flexible and stretchable, is not elastic. A metal foil, when stretched or bent, does not have shape memory to return itself to its original shape.

Furthermore, Byers uses sharp needles which penetrate nerves or other body portions. This penetration helps maintain contact during motion, but comes at a price. When implanted as a nerve cuff, Byers suggests that the penetration is necessary. Even when applied to surfaces of organs or tissues, penetration by the needles appears to be important to Byers. Such penetration will increase irritation, increase the potential for infection, and otherwise create medical difficulties if applied to the surface of the skin.

Third, it is submitted that Byers fails to provide an enabling disclosure which would enable one to make the described electrode with an elastic base or projections. At column 10, lines 29-30, Byers describes silicon, sapphire, or germanium as a suitable base. Indeed, it will be noted that Byers builds the electrode using semiconductor manufacturing technology. It is submitted that such ceramic materials are not elastic materials, even if a thin film of metal is desposited on them.

Further, the list of biomedical grade plastics listed in column 10, lines 32 and 33 are not asserted to be elastic and do not appear to be elastic. Indeed, they appear to be rigid materials.

Even in the capacitive embodiment, the preferred insulating layer is aluminum oxide, a ceramic which is not an elastic material (column 12, line 66 – column 13, line 15).

Own is not cited to and does not overcome these shortcomings of Byers.

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Accordingly, it is submitted that claim 1 and claims 2, 4, 6, and 13-16 dependent therefrom distinguish patentably and unobviously over the references of record.

Dependent claim 16, which calls for the elastic material to include an electrically conductive rubber distinguishes yet more forcefully over Byers and the other references of record. Using rubber needles in Byers will render the Byers device unsuitable for its intended purpose. First, the needles will not perform the function of piercing bundles of nerve fibers without damaging the nerve fibers. Second, the electrically conductive rubber raises issues regarding biocompatibility for implantable electrodes.

Claim 7 calls for an electrically conductive elastic layer. The metal foil layer 9 of Byers is not an elastic layer.

Claim 7 calls for flexible insulating layers. The silicon oxide layer 15 is a ceramic, not a flexible layer. The silicon base 7 is described as a conventional semiconductor substrate upon which the metal film 9 and the cones 12, 13 are grown. There is no suggestion that it be, and it is submitted, is not an elastic material.

Claim 7 calls for a plurality of metallic elements embedded in the electrically conductive elastic layer. In Byers, cones 12, 13, are grown on metal film 9 which, in turn, is grown on the ceramic substrate 7, 8. Claim 7 further calls for the tips of the metallic elements to extend through one of the flexible layers. The cones 12, 13 of Byers are neither embedded in nor extend through the base 7, 8.

Accordingly, it is submitted that Byers neither anticipates claims 7 or 10, nor renders dependent claims 8 or 9 obvious.

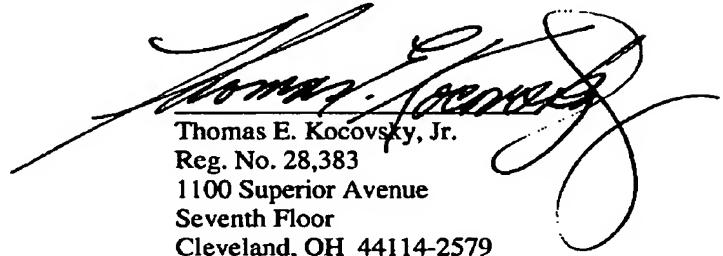
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CONCLUSION

For the reasons set forth above, it is submitted that all claims are not anticipated by and distinguish patentably and unobviously over the references of record. An early allowance of all claims is requested.

Respectfully submitted,

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